



SEP 21 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Cheryl L. Bagwell  
Director of Regulatory  
Chattanooga Group  
4717 Adams Road  
Hixson, TN 37343

Re: K051938

Trade/Device Name: Triton/Tru-Trac/TX Traction  
Regulation Number: 21 CFR 890.5900  
Regulation Name: Powered traction equipment  
Regulatory Class: Class II  
Product Code: ITH  
Dated: July 15, 2005  
Received: July 20, 2005

Dear Ms. Bagwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

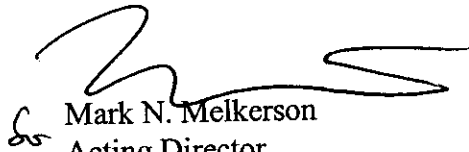
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Cheryl Bagwell

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Mark N. Melkerson  
Acting Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K  
 Device Name: Triton/Tru-Trac/TX Traction

Indications for Use:

The Triton/Tru-Trac/TX traction devices provide traction and mobilization of skeletal structures and skeletal muscles.

The Triton/Tru-Trac/TX traction devices provide a treatment in static, intermittent, progressive, regressive and cycling distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, wrist, shoulder). Therapeutic distraction can be applied in a variety of programmable patterns, cycles and functions.

The Triton/Tru-Trac/TX traction devices may be used to relieve peripheral radiation/sciatica and pain associated with:

- Protruding discs
- Bulging discs
- Herniated discs
- Degenerative disc disease
- Posterior facet syndrome
- Acute facet problems
- Radicular pain
- Prolapsed discs
- Spinal root impingement
- Hypomobility
- Degenerative joint disease
- Facet syndrome
- Compressions fractures
- Joint pain
- Discogenic pain

The Triton/Tru-Trac/TX traction devices achieve these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

Prescription Use ✓ AND/OR Over-The-Counter Use \_\_\_\_\_  
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

Page 1 of 1

**510(k) Number** K051938